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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/773,669

02/06/2004

Steffen Dubnack

ZEI-3226/500343.20238

7534

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7590

08/19/2009

REED SMITH, LLP

ATTN: PATENT RECORDS DEPARTMENT

599 LEXINGTON AVENUE, 29TH FLOOR

NEW YORK, NY 10022-7650

EXAMINER

EISEMAN, ADAM JARED

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

08/19/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/773,669	<b>Applicant(s)</b> DUBNACK ET AL.	
	<b>Examiner</b> ADAM J. EISEMAN	<b>Art Unit</b> 3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 July 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/6/2009 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-2 rejected under 35 U.S.C. 103(a) as being unpatentable over Ciaff (US 2003/0100932) in view of Raymond et al (US 5,775,331) and Gonzalez (US 6,685,729).

Ciaff discloses an apparatus for the diagnosis and therapy of neuro-muscular and other tissue disorders comprising: placing a probe in an area of body tissue of a person to be treated (paragraph [0012]); stimulating the area of body tissue by causing the probe to send to the area different electrical and/or electromagnetic stimulus (paragraph [0012]) which can be pre-adjusted or modulated (paragraph [0006]); identifying any pathologically changed tissue parts in the area of body tissue by identifying those tissue parts for which the person being treated provides no stimulus response or an unexpected stimulus response (paragraphs [0012]-[0013]); treating the

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area of body tissue wherein treatment comprises the probe selecting and/or removing any pathologically changed tissue parts (paragraph [0013]).

However, Ciaff does not disclose that if the tissue does not identify a pathologically changed tissue part, the probe is repositioned and new area of body tissue is stimulated; or that stimulation following repositioning can be carried out by iterative or continuous transmission of stimulus signals.

Raymond teaches a general method in tissue stimulation wherein a stimulus is applied, and if the stimulus does not identify a certain response, the probe is repositioned to a new area of body tissue to be stimulated again (column 5, line 8-column 6, line 60).

Gonzalez teaches testing brain tissue in an iterative test where tissue is stimulated, corrected of any defects, and re-stimulated/tested until functioning normally (column 11, lines 40-62; figure 1).

Regarding claims 1-2; it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ciaff to include a step of repositioning the probe as taught by Raymond in order to test all tissue areas of a patient for pathologically changed tissue. Furthermore, it would have been obvious to one of ordinary skill to use the method and technique of the Ciaff/Raymond combination on brain tissue as taught by Gonzalez in order to test nerve function in/to the brain.

Further regarding claim 2; Ciaff discloses that the device can be programmed/controlled to carry out iterative or continuous transmission of stimulus signals (paragraph [0011]).

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4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ciaff in view of Raymond and Gonzalez as applied to claims 1 and 2 above, and further in view of Zealear (US 4,817,628).

Ciaff as modified by Raymond and Gonzalez above teaches direct stimulation is carried out by alternating the treatment and positioning of the probe for tissue stimulation and the immediate evaluation of the stimulus response; however it does not disclose warning the user and/or interrupting the treatment during treatment of critical tissue areas.

Zealear teaches an iterative tissue testing method where the user is warned during treatment of critical tissue regions (column 13, line 67 - column 14, line 9).

Regarding claim 3, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Ciaff/Raymond/Gonzalez combination to warn the user during treatment of critical tissue regions as taught by Zealear in order to ensure the user isn't careless in the critical area.

### ***Response to Amendment***

The applicant's amendments and arguments/remarks have been fully considered but are moot in view of the new grounds of rejection.

The applicant's argument that the Ciaff/Raymond combination fails to disclose tissue stimulation in brain tissue is non-persuasive in view of the Gonzalez reference used in the rejections above. Gonzalez teaches using stimulation on the brain to test nerve and brain function, and thus it would have been obvious to one of ordinary skill in

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the art at the time of the invention to modify the Ciaff/Raymond combination for use in testing nerve/brain function.

The applicant's argument that Raymond does not disclose repositioning a single probe and that disclosure is too generic to disclose the specific situation of repositioning the probe is non persuasive. Raymond discloses alternating the stimulation site based on the evaluation of a response. One of ordinary skill in the art at the time of the invention would have known that in a single probe setup the probe would be repositioned in order to perform Raymond's technique of alternating the stimulation site. Furthermore, Raymond discloses that the site of stimulation is modified by evaluation of the response. One of ordinary skill in the art at the time of the invention would have been capable of setting their own standards as to what the evaluation of the response is based on, including testing for defects and or healthy tissue.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM J. EISEMAN whose telephone number is (571)270-3818. The examiner can normally be reached on Monday-Friday 9:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AE  
8/15/2009  
/A. J. E./  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736